Essai Clinique

Généré le 05 mai 2024 à partir de

Titre	Étude ouverte multicentrique de phase 2 pour évaluer l'efficacité et l'innocuité de ZN c3 chez les femmes adultes atteintes d'un carcinome utérin séreux récidivant ou persistant
Protocole ID	ZN-c3-004
ClinicalTrials.gov ID	NCT04814108
Type(s) de cancer	Utérus (sarcome)
Phase	Phase II
Type étude	Clinique
Médicament	ZN-c3
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dre Lucy Gilbert
Coordonnateur	Phuong-Nam (Nathalie) Nguyen 514-934-1934 poste 31975
Statut	Actif en recrutement
But étude	Il s'agit d'une étude de phase 2 visant à évaluer l'activité clinique, l'innocuité, la pharmacocinétique (PK) et les biomarqueurs associés de ZN-c3 chez les femmes adultes atteintes d'un carcinome séreux utérin récurrent ou persistant (CSU).
Critères d'éligibilité	• Females age ≥18 years of age at the time of informed consent. • Recurrent or persistent USC. • Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 0 or 1. • Measurable disease, defined as at least one lesion that can be accurately measured per revised Response Evaluation Criteria in Solid Tumors RECIST Guideline version 1.1 criteria. • Adequate hematologic and organ function. • Females of childbearing potential must agree to use an effective method of contraception per institutional standard prior to the first dose and for 90 days after the last dose of ZN c3.
Critères d'exclusion	• Prior treatment with a cell cycle checkpoint inhibitor. • Prior therapy with ZN-c3 or any other WEE1 inhibitor. • A serious illness or medical condition(s). • Unresolved toxicity of Grade > 1 attributed to any prior therapies (excluding ≤Grade 2 neuropathy, alopecia, or skin pigmentation). • Pregnant or lactating females (including the cessation of lactation) or females of childbearing potential who have a positive serum pregnancy test within 28 days prior to C1D1. • Subjects with active (uncontrolled, metastatic) second malignancies or requiring therapy. • 12-lead ECG demonstrating a corrected QT interval using Fridericia's formula (QTcF) of > 480 ms at screening, except for subjects with atrioventricular pacemakers or other conditions (e.g., right bundle branch block) that render the QT measurement invalid. • History or current evidence of congenital or family history of long QT syndrome.